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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,139	12/09/2003	Sharat Singh	BEH-7245	4747

7590

07/28/2004

Dade Behring Inc.
1717 Deerfield Road
Deerfield, IL 60015

EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/730,139

Applicant(s)

SINGH ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-92 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 45-92 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/09/2003</u> . | 6) <input type="checkbox"/> Other: ____. |

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1) References C14 and C15 of form PTO-1449 have not been considered since they are not present in the file of this application nor were they submitted in application S.N. 09/985,254.

2) In claim 57, "AR" should be changed to "Ar".

3) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

4) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6) Claims 45-64, 66-76, 78-88 and 90-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no written description in the specification to support the generic concept recited in instant claim 45. The description of the invention as it appears in the specification neither describes nor supports the use of the "compound" recited in claim 45, ii) nor the compound of claim 69 in an assay; the description of the specification requires the use of the compounds having the structures depicted on pages 6, 7 and 37. The description of the assay method of the invention also requires the use of particles and a binding

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member which is specific for the analyte of interest (see the specification at page 7, lines 10 *et seq*; page 33, lines 21 *et seq*; page 50 line 32 *et seq*).

7) Claims 45-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The use of the term "oxygen group" in claim 45, ii) is confusing since it is not clear what is intended; for example, the term could imply an "oxygen" atom or oxygen as part of an unspecified type of "group".

b) Claim 45 is indefinite and incomplete for the reason that no step is required in which the presence or absence of the "analyte" affects the production of luminescence, i.e. the "treating", "exciting" and "detecting the amount of luminescence" steps are in no way related to the presence/absence of the "analyte".

c) Claim 53 is indefinite and confusing for the reason that the specificity (i.e. what it binds with) of the "specific binding pair member" is not identified.

d) In claim 53, it is unclear what is meant by the term "said specific binding pair member being independently selected for each of said latex particulate materials". First, claim 50 requires only a single "particulate material" so that what is intended by the reference to multiple "latex-particulate materials" is unclear. Second, since the method of claim 45 is directed to an assay for a single analyte, the implication that there is more than one specific binding member for the analyte ("independently selected for each") is inconsistent with the independent claim. These problems also exist for claims 54, 65, 66, 77, 89 ("individually associated with") etc.

e) In claim 69, it is unclear what is meant by the term "organic radical" and "taken together to form a ring". The structural requirements for these terms are unclear.

f) In claim 81, it is unclear what the difference is between the terms "alkyl" and "alkyl radical". The exact structure and function of the "radical" cannot be determined.

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8) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9) Claims 45-92 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-8 of U.S. Patent No. 6,180,354. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 45 of the instant application which "comprises" the steps of "providing" reactants, "treating" with light and "detecting the amount of luminescence" is inclusive of the methods recited in the claims of the patent. As an example, claim 65 of the instant specification and claim 3 of the patent require the use of the same combination of "specific binding pair member", "photosensitizer" and "latex particulate materials" in the same analytical method.

10) An inquiry of a general nature which is **not related to the prosecution on the merits** should be directed to Technology Center 1600 telephone number (571) 272-1600. The general fax number for the USPTO is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823.

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July 27, 2004


Mary (Molly) E. Ceperley
Primary Examiner
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